

Isofield CRN+

Sterile 400mm (16")

Cleanroom Nitrile Gloves

PRODUCT INFO

GMP Grade A compatible
 ISO Class 4 & 5 compatible
 Sterile
 Nitrile
 White colour
 Elbow length 400mm (16")
 Ambidextrous
 Textured palm and fingers
 Beaded cuff
 Tested against a range of chemotherapy drugs
 Complies with EU food grade Regulation (EU)
 No 10/2011

QUALITY ASSURANCE

Manufactured in a facility operating under
 ISO 9001:2015 quality management system

Processed in a NEBB certified ISO Class 5
 Cleanroom

Physical properties comply with European
 medical glove standard EN455-2:2015

STERILIZATION

Gamma irradiation, Minimum 25 kGy

SHELF LIFE

Three (3) years from date of manufacture

STORAGE

Store in a dry, cool place (<40°C) away from
 direct sunlight.

Do not expose open cartons to prolonged
 direct fluorescent light

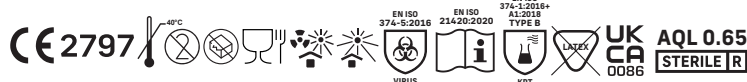
PACKING

One pair per inner PE wallet,
 One PE wallet per sealed PE pouch,
 10 pouches per PE bag,
 20 sealed PE bags per lined carton (200 pairs)

PRODUCT CODE

REF 20240

SMALL	6.0 - 6.5	20240S
MEDIUM	7.0 - 7.5	20240M
LARGE	8.0 - 8.5	20240L
XLARGE	9.0	20240XL



PHYSICAL PROPERTIES

THICKNESS, SINGLE WALL	MM*	MILS	TEST METHOD
Finger tip	0.17	6.69	EN455-2:2015
Palm	0.11	4.33	
Cuff	0.09	3.54	

* +/- 0.02mm

LENGTH	MIN	TYPICAL	TEST METHOD
From tip of middle finger to edge of cuff	390mm	400mm	EN ISO 21420 :2020

STRENGTH PROPERTIES	FORCE AT BREAK	TEST METHOD
Throughout shelf life	≥ 6.0 N	EN455-2:2015

FREEDOM FROM HOLES	PERFORMANCE	TEST METHOD
Acceptable Quality Level (AQL)	0.65 - Level 3 of 3	EN374-2:2016

CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm²)	1800	IENT-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm²)	TEST METHOD
Fluoride (F)	ND	IENT-RP-CC005.4
Chloride (Cl)	0.031	
Bromide (Br)	ND	
Nitrate (NO ₃)	0.500	
Phosphate (PO ₄)	0.062	
Sulphate (SO ₄)	0.012	
Sodium (Na)	0.050	
Ammonium (NH ₄)	0.020	
Potassium (K)	0.064	
Calcium (Ca)	0.432	
Magnesium (Mg)	ND	
Zinc (Zn)	ND	

* ND = Not Detected

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	BREAKTHROUGH TIME	TEST METHOD
Carmustine	66min	ASTM D6978-05
Cisplatin	>240min	ASTM D6978-05
Cyclophosphamide	>240min	ASTM D6978-05
Doxorubicin HCl	>240min	ASTM D6978-05
Etoposide	>240min	ASTM D6978-05
Fluorouracil	>240min	ASTM D6978-05
Methotrexate	>240min	ASTM D6978-05
Paclitaxel	>240min	ASTM D6978-05
Thiotepa	1min	ASTM D6978-05